

CLAIMS

1. A pharmaceutical composition comprising as an active ingredient a recombinant polyclonal antibody or a mixture of individual monoclonal antibodies or an isolated or purified polyclonal antibody capable of reacting with or binding to an allergen together with one or more pharmaceutically acceptable excipients.
2. A pharmaceutical composition according to claim 1 wherein the active ingredient is a recombinant polyclonal antibody.
3. A pharmaceutical composition according to claim 1 wherein the active ingredient is a mixture of individual monoclonal antibodies.
4. A pharmaceutical composition according to claim 1 wherein the active ingredient is an isolated or purified polyclonal antibody.
5. A pharmaceutical composition according to any of claims 1-4, which composition is free of the allergen to which the antibody is reactive or binds.
6. A pharmaceutical composition according to any of claims 1-5 comprising at least one pharmaceutically acceptable excipient capable of effecting topical application of said recombinant polyclonal antibody or said mixture of individual monoclonal antibodies or said isolated or purified polyclonal antibody.
7. A pharmaceutical composition according to claim 5, which is intended for topical administration to the oropharynx, nasal cavity, respiratory tract, gastrointestinal tract, conjunctival mucosa, vagina, urogenital mucosa, or for dermal application.
8. A pharmaceutical composition according to claim 7, wherein the respiratory tract comprises the nasal, oral, pharyngeal, bronchial or alveolar mucosa.
9. A pharmaceutical composition according to any of claims 1-8, which is provided as a solution, dispersion, powder or in the form of microspheres.

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10. A pharmaceutical composition according to claim 2, wherein the recombinant polyclonal antibody is generated by phage display technology.

5 11. A pharmaceutical composition according to claim 10, wherein the recombinant polyclonal antibody is generated under such conditions that the immunoglobulin heavy chain variable region and light chain variable region gene segments are linked together in a parental library in order to allow for the bulk transfer of variable region light chain and heavy chain gene pairs from one vector to another, while
10 allowing stable pairing of specific immunoglobulin variable region light chain and heavy chain gene segments as they are present upon selection from the parental library of immunoglobulin variable region light chain and heavy chain gene segment pairs encoding antibody molecules capable of reacting with or binding to an allergen.

15 12. A pharmaceutical composition according to claim 10, wherein the recombinant polyclonal antibody is generated under such conditions that the immunoglobulin heavy chain variable region and light chain variable region gene segments are linked together in order to allow for the bulk transfer of specific variable region light
20 chain and heavy chain gene pairs from one vector to another, while allowing stable pairing of specific immunoglobulin variable region light chain and heavy chain gene segments as they are present in the original polyclonal immune response of an animal or human individual.

25 13. A pharmaceutical composition according to any of claims 1-12, wherein the allergen is an allergen of house dust mites, e.g. *Dermatophagoides farinae* or *D. pteronyssimus*; dander from cat, dog or horse; tree pollen, e.g. pollen from birch (*Betula alba*), alder, hazel, oak, willow, plane, beech, elm, maple, ash, mugwort (*Artemisia*) and hornbeam; grass pollen, e.g. pollen from timothy grass (*Phleum
30 pratense*), bluegrass (*Poa pratense*), rye grass (*Lolium perenne*), Orchard grass (*Dactylis glomerata*), ragweed (*Ambrosia artemisiifolia*), sweet vernal grass

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(*anthoxanthum odoratum*), and rye (*Secale cereale*); or fungi (e.g. *Alternaria*, *Aspergillus*, *Cladosporium* and *Penicillium*).

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14. A pharmaceutical composition according to any of claims 1-13 comprising the
5 recombinant polyclonal antibody or the mixture of monoclonal antibodies or the isolated or purified polyclonal antibody in an amount in the range of 1 μ g to 1 g, preferably 1-1000 μ g, more preferably 2-500 μ g, even more preferably 5-50 μ g, most preferably 10-20 μ g per unit dosage form.

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15. Use of a polyclonal antibody capable of reacting with or binding to an allergen for the manufacture of a pharmaceutical composition for the prophylaxis or treatment of allergy.

15 16. Use of a polyclonal antibody capable of reacting with or binding to an allergen for the manufacture of a pharmaceutical composition for prophylactic or therapeutic induction of tolerance to the allergen.

17. Use of a polyclonal antibody capable of reacting with or binding to an allergen
20 for the manufacture of a pharmaceutical composition for modulation of the immune system.

18. The use according to any of claims 15-17, wherein the polyclonal antibody is a recombinant polyclonal antibody

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25 19. The use according to any of claims 15-17, wherein the polyclonal antibody is a mixture of individual monoclonal antibodies

20. The use according to any of claims 15-17, wherein the polyclonal antibody is
30 an isolated or purified polyclonal antibody.

21. The use according to any of claims 15-21, wherein the composition is intended for topical administration to the oropharynx, nasal cavity, respiratory tract, gastrointestinal tract, conjunctival mucosa, vagina, urogenital mucosa, or for dermal application.

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22. The use according to any of claim 15-21, wherein the polyclonal antibody is included in the composition in an amount in the range of 1 μ g to 1g, preferably 1-1000 μ g, more preferably 2-500 μ g, even more preferably 5-50 μ g, most preferably 10-20 μ g per unit dosage form.

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23. A method of preventing or treating allergy, which comprises administering to a patient in need thereof a composition according to any of the claims 1-14 comprising a sufficient amount of a polyclonal antibody capable of reacting with or binding to an allergen to which the patient has shown or is predisposed to develop an allergic reactions.

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24. A method of inducing tolerance to an allergen which comprises administering to a patient who would untreated be likely to show allergic reaction to the allergen a composition according to any of the claims 1-14 comprising a sufficient amount of a polyclonal antibody capable of reacting with or binding to the allergen and induce tolerance to the allergen in the patient.

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